

WHE/CRS

Office Action Summary	Application No.	Applicant(s)
	08/444,790	Brockhaus et al
	Examiner T Michael Nisbet	Group Art Unit 1806

Responsive to communication(s) filed on May 19, 1995

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 44-55 is/are pending in the application.

Of the above, claim(s) 55 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 44-54 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) 07/580,013.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

PTO-948

RESPONSE DUE: May 1, 1996

PATENT DEPARTMENT

FEB 22 1996

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III. DETAILED ACTION

1. Applicant is reminded of the need to update the status of the previous parent applications
2. Claims 1-43 have been cancelled.
3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 44-54, drawn to proteins , classified in Class 530, subclass 350+.
 - II. Claim 55, drawn to a method of purification, classified in Class 436, subclass 505.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and II are separate and distinct from one another as a product and a method of making that product. The two can be established as distinct if the product can be made in a variety of different ways. In the instant case, the product is capable of being product recombinantly or by chemical synthesis. Consequently, the product of Group I is capable of separate manufacture by two methods besides that claimed in Group II. Accordingly restriction is proper.

Because these inventions are distinct for the reasons given above and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Catherine Roseman on January 3, 1996 a provisional election was made without traverse to prosecute the invention of Group I, claim 44-54. Affirmation of this election must be made by applicant in responding to this Office action. Claim 55 is withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

7. Claims 44-55 were submitted in the preliminary amendment filed 5/19/95. Claims 44-54 are currently under consideration.

8. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. § 119. The certified copies have been filed in parent application, Serial No. 07/580,013, filed on September 10, 1990.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 44-47 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Stauber et al. [JBC 263(35):19098-19104 (1988)]

Stauber et al. teach a homogeneous preparation of a human tumor necrosis factor receptor, see entire document. Note that the receptor is insoluble, but is solubilized by a variety of detergents with full retention of binding activity, see page 19099, column 1. Claim 49 is directed to a protein. While the protein of the reference was not obtained by recombinant methods, it nevertheless appears to be the same. The purification or production of a protein by a particular process does not impart novelty to a protein when the same protein is taught by the prior art.

11. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude

patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

12. Claims 48-54 are rejected under 35 U.S.C. § 103 as being unpatentable over Wallach et al. in view of Capon et al. [wo 89/02922]. Briefly the claims are directed to a recombinant TNF fusion protein containing heavy chain human immunoglobulin sequences, and antibodies to the TNF protein and fusion protein. Wallach et al. teach a homogeneous preparation of a human tumor necrosis factor receptor, see entire document. Note that, the Wallach et al. teach salts, functional derivatives and active fractions of the TNF receptor which would inherently include insoluble preparations, see abstract. Wallach et al. teach a 40-80 kDa protein determined by gel filtration which would reasonable be approximately 55 kDa by nonreducing SDS-PAGE. Wallach et al. teach a partial sequence of the TNF receptor protein on page 3. This sequence is exactly the same as amino acids 12-27 disclosed in figure 1. It therefore appears that Wallach et al. have the same protein as claimed. Wallach et al. teach a homogeneous protein obtained by recombinant methods, see pages 8-11. Wallach et al. teach a 40-80 kDa protein determined by gel filtration

which would inherently be approximately 55 kDa by nonreducing SDS-PAGE. Wallach et al. teach a partial sequence of the TNF receptor protein on page 3. This sequence is exactly the same as amino acids 12-27 disclosed in figure 1. It therefore appears that Wallach et al. have the same protein as claimed. Wallach et al. teach a homogeneous protein obtained by recombinant methods, see pages 8-11. Neither or Wallach et al. teach a TNF fusion protein with a human immunoglobulin constant domain. However, Capon et al. teach adhesion variants. These variants contain active regions of protein molecules fused to the N-terminus of the constant region of immunoglobulin in place of the variable region(s) - retaining at least functionally active hinge, CH₂ and CH₃ domains of the constant region of an immunoglobulin heavy chain, see page 10. Capon et al. teach suitable companion immunoglobulin combining sites and fusion partners are obtained from IgG-1, -2, -3 or -4 subtypes IgA, IgE, IgD or IgM, see page 13. Capon et al. teach that successful strategies in the development of drugs for the treatment of many receptor mediated abnormalities has been the identification of antagonists which block binding of the natural ligand. Since adhesions are normally present only on cell surfaces, it would be desirable to produce adhesions in a form which is more stable in the circulation. Therefore it would have been prima facia obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Wallach et al. to those of Capon et al. in order to obtain a soluble TNF-immunoglobulin fusion protein for the treatment of TNF related pathologies.

13. Applicant is reminded that the translation of the non-English patent publication EP 464 533 was not considered because applicant has not complied with the requirements for information disclosure.
14. Both LeMaire (5,344,915) and Smith (5,395,760) teach TNF binding protein sequences which are not the same as those set forth in fig. 19.
15. No claims are allowed.
16. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4227.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Nisbet whose telephone number is (703) 308-4204 from 9:00 am to 5:00 pm weekdays with the exception of alternating Mondays. If the examiner cannot be reached, the supervisor, Marion Knode, may be contacted at phone number (703)308-4311.

The number for facsimile submission of papers has changed. The new fax number for Art Unit 1806 is (703) 305-7401. Please provide the serial number, application title, examiner's name, and art unit on the fax cover sheet to expedite clerical processing. In addition, all cover sheets should be marked **DRAFT** or **OFFICIAL** as appropriate.

Any informal communications of a **nonconfidential** nature can be communicated to Examiner Nisbet electronically at the following address, tnisbet@uspto.gov.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Serial No.: 08/444,790
Art Unit: 1806

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TMN
11 January 1996



PAULA K. HUTZELL
PRIMARY EXAMINER
GROUP 1800